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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,781	11/17/2003	Sheena May Loosmore	454313-3161.5	2429

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,781	LOOSMORE ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *10/24/05, 11/17/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

Were color figures submitted with this application? If so, color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> **The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.**

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Double Patenting

Claims 1-29 of this application conflict with claims 1-29 of Application No. 10/679520. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-29 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-29 of copending Application No. 10/679520. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-27 of

copending Application No. 10/676502. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the copending claims, or constitute obvious variations of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 17-20, 22, 25, 26, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 18 recite the limitation "vaccine composition." There is no antecedent basis for this limitation in parent claim 1. Claim 19 lacks antecedent for "the adjuvant."

Claims 18 and 20 refer to "the composition according to" a prior claim, but the cited claims are drawn to methods, not compositions.

Claim 20 refers to response "against another pathogen", but nothing in the claim or the parent claims refers to a component from another pathogen. Is the intent to induce a nonspecific immune response, or is something missing from the claims?

Claim 25 lacks antecedent for "(a) and (b)," so it is totally unclear what is required in the kit.

These problems affect the dependent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 16, 17, 18, 29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chang et al US 2003/0022849, see Examples 9-11.

Claims 1, 7, 10-12, 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Kinney et al W) 01/60847, see example 6.

Claims 1-3, 7, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamshikov et al (Gene 149:193-201). These claims are drawn to compositions containing only one component, a vector encoding and expressing certain West Nile Virus genes. Yamshikov teaches a poxvirus vector encoding and expressing the West Nile products PrM and D, see for example pages 197-199 and Figures 5-6. Although the reference does not teach the intended use recited in the claim, the claims are drawn to a product, not a method of use, and the reference meets each and every definite limitation of the claimed product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinney et al WO 01/60847. Kinney explicilty suggests immunization using a chimeric virus expressing WNV proteins, see page 7. It would have been within the ordinary skill of the art to carry out this suggestion with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al US 2003/0022849. Claims 10 and 11 differ from Chang in specifying that the WNV sequence comes from a specific Genbank reference sequence. Claim 12 differs from Chang in requiring that the signal peptide comes from prM. However, given the successful results of DNA vaccination reported by Chang, it would have been obvious to substitute the sequence of any known WNV isolate for the specific sequence used by Chang, and to use an endogenous WNV signal sequence instead of the functionally equivalent vector-encoded JEV signal sequence, with reasonable

expectation of success. Claim 13 requires an adjuvant. However, Chang explicitly suggests including an immunostimulatory DNA sequence, see page 7, paragraph 0066. Therefore it would have been obvious to carry out this suggestion, with reasonable expectation of success.

Claims 1-13, 15-18, 20, are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Paoletti et al 5,744,141, Chang US2003/0022849, and Paoletti 5,505,941. Paoletti '141 teaches recombinant poxviruses (including avipoxviruses) expressing the PrM, M, and E genes of flaviviruses, teaches the secretion of particles containing M and E from cells infected with the constructs, and teaches use of the viruses for immunogenic compositions. This differs from the claimed invention in that Paoletti did not construct a poxvirus expressing the genes of the West Nile species of flavivirus. However, Chang teaches an immunogenic nucleic acid composition to induce an immune response against West Nile virus. Paoletti '941 teaches particular advantages of avipoxviruses such as fowlpox and canarypox, for immunizing mammals or avians. In light of the teachings of Chang, it would have been within the ordinary skill of the art to modify Paoletti '141 by use of West Nile coding sequences in a poxivrus construct, for the purpose of raising an immune response against the West Nile species of flavivirus, with reasonable expectation of success. Furthermore, in view of the knowledge in the art that West Nile Virus infects both mammals and birds, it would have been obvious to choose a poxvirus that has been shown to successfully induce an immune response in mammals and birds, such as the

avipoxviruses taught by Paoletti '941. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 21, 22, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Paoletti et al 5,744,141, Chang US2003/0022849, and Paoletti 5,505,941 as applied to claims 1-32, 36 above, and further in view of Ramshaw et al (Immunology Today 21:163-165, 2000). These claims call for a prime/boost immunization, or a kit containing materials for the same. However, Ramshaw teaches that it was known in the art to improve humoral or cell-mediated immune responses by administering various permutations of DNA, poxvirus, and protein immunogens in a prime/boost method. Therefore it would have been obvious to make and use prime/boost compositions, to obtain the known and expected improved responses. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al 5,744,141, Chang US2003/0022849, and Paoletti 5,505,941 as applied to claims 1-32, 36 above, and further in view of Paoletti 5338683. These claims differ from the above in requiring the animals to be tested for the presence or absence of a WNV product or antibody thereto which is not included in the immunizing composition. However, it was known in the art that vector vaccines expressing only a subset of the proteins of the target pathogens can be used to discriminate between vaccinated animals and naturally infected animals, see for example column 46, lines 2-8. Therefore further modification to test for vaccination versus infection is seen as obvious, absent unexpected results.

Claims 14, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti et al 5,744,141, Chang US2003/0022849, and Paoletti 5,505,941 as applied to claims 1-32, 36 above, and further in view of Audonnet et al WO 99/44633. The English language equivalent US 6713068 is cited for convenience, but the effective date of the WO publication is relied upon. These claims differ from the above in further requiring an adjuvant, specifically a carbomer. Audonnet et al teaches use of a carbomer adjuvant with live recombinant virus vaccines for improved immune response, see for example the abstract and the Examples. Therefore it would have been obvious to further modify the invention for improved immune response, absent unexpected results.

Claims 1-11, 16-18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti (Proc Natl Acad Sci USA, 1996, 93:11349-11353), in view of both Goverdhan et al. (Acta Virol, 1992, 36: 277-283) and Ostlund et al. (Vet Clin North Am Equine Pract, 2000, 16: 427-44, Abstract), as evidenced by Paoletti et al. (US Patent No. 5,756,103).

Paoletti teaches a method of inducing an immunological response against Japanese encephalitis virus (JEV) by administering to a subject an immunogenic composition comprising NYVAC and recombinant canarypox (i.e., ALVAC, see also Paoletti et al., US Patent No. 5,756,103, Fig 17, Fig. 31, and Example 15) encoding for the polyprotein prM/M, E of JEV (p. 11351, column 2 bridging p. 11352, column 1). Paoletti does not teach West Nile virus. However, Goverdhan teaches that immunization with JEV protects animals against WNV (Abstract). Therefore, it would have been obvious to one of skill in the art to develop a vaccine against WNV according

to the teachings of Paoletti by replacing the JEV prM/M, E with the WNV prM/M, E, with a reasonable expectation of success. The motivation to do so is provided by Ostlund who teach the need for developing an anti-WNV vaccine to protect horses against WNV infection (Abstract). One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a vaccine because the art teaches the successful engineering and using of such vaccines for JEV, which is very closed related to WNV. It is noted that such an anti-WNV vaccine would necessarily comprise the nucleotide sequences recited in claims 10 and 11, since, at the time the invention was made those sequences were already deposited as GenBank AF 196835. Thus, the claimed invention was prima facie obvious at the time the invention was made.

Claims 1-12, 16-18, and 22 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to claims 1-11, 16-18, and 22 above, in further view of both Stocks et al. (J Virol, 1998, 72: 2141-2149) and Chang et al. (J Virol, 2000, 74: 4244-4252).

Paoletti taken with Goverdhan and Ostlund do not teach a signal peptide, as recited in claim 13. Stocks teaches the importance of adequate posttranslational processing of prM for the immunogenicity of the vaccine (p. 2141, column 2, first paragraph). Chang teaches the inclusion of the signal peptide of prM in their anti- JEV vaccine for proper processing of prM (p. 4245, column 1, first paragraph, p. 4249, column 2, first and second paragraphs, and p. 4249, column 2 bridging p. 4250). It would have been obvious to one of skill in the art, at the time the invention was made, to

include the prM signal peptide in the recombinant vaccine, with a reasonable expectation of success. The motivation to do so is provided by both Stocks and Chang , who teach the lack of immunogenicity for constructs not optimized for proper processing of prM. One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a vaccine because the art teaches the successful use of signal peptides in vaccines directed against flaviviruses.

It is noted that such an anti-WNV vaccine would necessarily comprise the nucleotide sequences recited in claim 13, since, at the time the invention was made those sequences were already deposited as GenBank AF 196835. With respect to the limitation of plasmid as recited in claim 29, Paoletti taken with Goverdhan and Ostlund do not teach it. Chang teaches plasmid-based anti-JEV vaccines (Abstract, p. 4244, column 2). It would have been obvious to one of skill in the art, at the time the invention was made, to use a plasmid DNA vaccine as taught by Chang , with a reasonable expectation of success. The motivation to do so ids provided by Chang who teach that a single injection with plasmid DNA vaccine induced a virus-specific antibody response, as compared to vaccination using a virus that require multiple immunizations (p. 4244, column 2). One of skill in the art would have been expected to have a reasonable expectation of success in making and using such a vaccine because Chang teaches the efficiency of plasmid-based vaccines to induce a robust antibody response. Thus, the claimed invention was prima facie obvious at the time the invention was made.

Claims 1-11, 13, 14, 16-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to

claims 1-11, 16-18, and above, in further view of Mumford et al. (Epidemiol Infect, 1994, 112: 421-437, Abstract).

Paoletti taken with Goverdhan et al and Ostlund et al do not teach a carbomer as an adjuvant. Mumford teaches carbomer. It would have been obvious to one of skill in the art, at the time the invention was made, to use carbomer as an adjuvant, with a reasonable expectation of success. The motivation to do so is provided by Mumford et al. who teach that horses were protected against equine influenza when vaccinated in the presence of carbomer, as compared with other adjuvants. One of skill in the art would have been expected to have a reasonable expectation of success because Mumford teaches the efficiency of such an adjuvant. Thus, the claimed invention was prima facie obvious at the time the invention was made.

Claims 1-11, 15-18, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to claims 1-11, 16-18, and 22 above, in further view of Varga et al. (Veterinary Microbiol, 1997, 56: 205-212).

Paoletti taken with Goverdhan and Ostlund do not teach a bivalent vaccine, as recited in claim 15. Varga teaches a bivalent vaccine comprising EHV-2 and R. equi serotype 1 strain to protect horses from infection by both viruses (Abstract, p. 20, p. 210, Discussion). It would have been obvious to one of skill in the art, at the time the invention was made, to use bivalent vaccine, with a reasonable expectation of success. The motivation to do so is provided by Varga who teach that protection against two different viruses can be achieved by using a bivalent vaccine. One of skill in the art

would have been expected to have a reasonable expectation of success because the art teaches the successful use of multivalent vaccines to achieve protection against different pathogens. Thus, the claimed invention was prima facie obvious at the time the invention was made.

Claims 1-11, 16-18, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti taken with Goverdhan et al. and Ostlund et al., as applied to claims 1-11, 16-18, and 22 above, in further view of Ruitengerg et al. (Vaccine, 2000, 18:1367-1373).

Paoletti taken with Goverdhan and Ostlund do not teach prior administration of a WNV isolated antigen, as recited in claim 21. Ruitengerg teaches a better protection by administering to the subject a plasmid encoding EHV-1 glycoprotein D, followed by a recombinant virus expressing the glycoprotein D (Abstract, p. 1367 bridging p. 1368). It would have been obvious to one of skill in the art, at the time the invention was made, to use such an immunization scheme, i.e., to obtain protection against WNV by administering to the animal a plasmid encoding for a WNV antigen or an isolated WNV antigen followed by a recombinant anti-WNV vaccine, with a reasonable expectation of success. The motivation to do so is provided by Ruitengerg who teach that a better protection against can be achieved in this way. One of skill in the art would have been expected to have a reasonable expectation of proper protection against pathogens. Thus, the claimed invention was prima facie obvious at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/2/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER